

## REMARKS

### Amendments

The specification has been amended to include priority information.

Claim 9 has been canceled without prejudice or disclaimer. Claims 1-6, 10, 12-20, 23, 24 and 26-30 have been amended. Claims 2-6, 10, 12-20 and 27-30 have been amended to re-insert the word "claim," which in each case was part of the original claim. The omission of the word "claim" from these claims in the prior amendment was an inadvertent typographical error, and not an intended amendment which lacked proper identification as such. The present amendment is made merely to clarify the record.

Claims 1 and 26 have been amended to relate to methods in which a water-soluble polymeric material is one or more chosen from the group consisting of water-soluble polysaccharides and water-soluble vinyl polymers. Support for this amendment can be found at least at page 6, first full paragraph. Claim 10 has been amended to relate to a method in which water-soluble polymeric material is selected from one or more of poly(vinyl alcohol) and dextran; support for this amendment can be found at least at previous claim 10. Claims 1, 23 and 26 have been amended to delete "in less than 107 seconds" from the claims.

Applicants submit that no new matter has been added by way of the amendments. With entry of the amendment, claims 1-6, 10, 12-20 and 23-30 will be pending in the application.

### Examiner Interview

Applicants thank the Examiner for courtesies extended in the telephonic interview with Applicants' representatives on April 14, 2011. During the interview, and as discussed in the Examiner Interview Summary mailed on April 18, 2011, the current rejections under 35 U.S.C. § 112, first paragraph and 35 U.S.C. § 102(b) were discussed, but no agreement was reached.

### Rejection under 35 U.S.C. § 112

Claims 1-6, 9-10, 12-20 and 23-30 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner argued that "the limitation '...able to substantially fully dissolve in water at 20°C in less than 107 seconds' ... is not found anywhere in the original specification or claims, and thus is not supported by the disclosure of the application." Office Action at pp. 2-3. Regarding Applicants' arguments that the data provided in a declaration demonstrated that porous materials that were prepared in accordance with the disclosure inherently possessed the claimed dissolution properties, the Examiner argued that "in order for the property to be

inherently contained within the invention, the claimed property must be present each and every time, in each and every circumstance, for the porous materials produced according to the method of claim 1." Office Action at page 12.

Applicants respectfully disagree with the rejection. According to MPEP § 2163 the written description requirement is satisfied when, "a patent specification . . . describe[s] the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention."

While Applicants believe the language of the previous claims satisfied the requirements of 35 U.S.C. § 112, first paragraph, claim 1 has been amended as noted above, without acquiescing to the rejection and solely to expedite prosecution. In particular, independent claims 1 and 26 have been amended to relate to a method in which the water-soluble polymeric material is one or more chosen from the group consisting of water-soluble polysaccharides and water-soluble vinyl polymers, and the phrase "in less than 107 seconds" has been deleted from claims 1, 23 and 26. Applicants submit that claims 1, 23, and 26 comply with the written description requirement, as do the relevant rejected dependent claims (e.g., claims 2-6, 9-10, 12-20 and 24, 25, and 27-30).

Contrary to the Examiner's position, the specification adequately informs one of skill in the art that the inventors had possession of the claimed invention. Claims 1 and 26 relate to methods for producing water-soluble porous materials and subsequently identify classes of water soluble materials that can be used. The classes of water soluble polymeric materials are clearly contemplated by the inventors as useful in the method of claim 1. Further, while one of skill in the art would certainly understand that a "water-soluble porous polymeric material" would not include a "water-insoluble porous polymeric material," Applicants have further amended the language of claim 1 to clarify certain physical characteristics of water-soluble porous polymeric material (e.g., polymers are substantially free of cross-linking, since cross-linking can decrease polymer solubility). While the above discussion has focused on the language of pending claims 1 and 26, this rejection is applied to the relevant dependent claims only in light of the language of the independent claims.

Therefore, in light of the above, one of skill in the art will clearly recognize that the inventors had possession of the claimed invention as of the filing date of the application. Thus, the pending claims meet the written description requirement of 35 U.S.C. § 112. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejection under 35 U.S.C. § 102**

Claims 1-6, 9-10, 13-15, 17-20 and 26 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Application No. 2003/0134918 to Ko et al. ("Ko").

Ko discloses compositions and methods of making absorbent polymeric foams using super critical fluids. Ko at paragraph [0008]. The Examiner argues that "Ko et al. teach that crosslinking materials are optional components in the materials of the invention (paragraph [0022]). Given this teaching, one of ordinary skill in the art would at once envisage porous materials which contain crosslinking and porous materials which do not contain cross linking. If one of ordinary skill in the art is able to 'at once envisage' the specific compound within the generic chemical formula, the compound is anticipated. See MPEP 2313.02." Office Action at paragraph 12. Applicants respectfully disagree with the Examiner's statement and traverse the rejection.

**Independent claim 1**

Independent claim 1, as amended, reads as follows:

1. A method for producing a water-soluble porous, polymeric material comprising the steps of:

- (a) providing a C/W emulsion comprising an aqueous phase, a matrix building material in the form of a water-soluble polymeric material, a surfactant and a liquid CO<sub>2</sub> phase;
  - (b) at least partially freezing the aqueous phase;
  - (c) gasifying CO<sub>2</sub> from the liquid CO<sub>2</sub> phase to produce an intermediate porous material;
  - (d) venting the gasified CO<sub>2</sub> from the intermediate porous material;
- and
- (e) freeze drying the intermediate porous material at least substantially to remove the aqueous phase and to form the water-soluble porous material; wherein said water-soluble polymeric material is one or more chosen from the group consisting of water-soluble polysaccharides and water-soluble vinyl polymers, and is substantially free of cross-linking such that said water-soluble porous material is able to substantially fully dissolve in water at 20 °C.

Applicants respectfully disagree with the Examiner's contention that one of skill in the art viewing Ko would immediately envision porous materials that are water-soluble and substantially free of cross-linking. The sentences preceding the statement in Ko to which the Examiner refers are reproduced below, with emphasis added:

[0022] As used herein, "cross-linking monomer" means a compound having at least two polymerizing unsaturated groups in the monomeric unit. Though the organic unsaturated carboxylic acid or salt thereof, particularly acrylic acid or a

salt thereof **may undergo self-crosslinked superabsorbent polymer**, a cross linking agent may **also** be added to crosslink the polymerized material in the oil-in-water type inverse high internal phase emulsion.

The passage states that a polymer may undergo self-crosslinking, but that a crosslinking agent may additionally be included. Accordingly, the paragraph suggests that in the event that the polymer does not itself undergo self-crosslinking, a cross-linking agent is added in order to initiate cross-linking of the polymer. This would be the case, for example, when monomers are used that do not undergo self-crosslinking, so that the objective of Ko (e.g., generating absorbent polymeric foams) can be achieved. Accordingly, the passage cited by the Examiner would not lead one of skill in the art to envision materials that are water soluble and free of crosslinking, particularly when one considers the reference as a whole (*vide infra*).

Furthermore, for the same and similar reasons as those that have already been made of record, Applicants believe that it is clear that the general teachings of Ko relate to absorbent articles, which would not be substantially water-soluble (if at all). In order to generate absorbent articles that do not dissolve upon exposure to an aqueous medium, crosslinking is often required as is well-appreciated in the art. Other passages of Ko clearly teach the use of a crosslinker, as follows:

[0055] The water phase of the I-HIPE or HIPE comprises from about 20% to about 80% by weight of a monomer component, **from about 0.01% to about 5% of a cross-linking agent**, and from about 1% to 10% of a water-soluble oxidizing initiator or from about 1% to 10% of a water-soluble reducing initiator, and from about 0.01% to about 5% of an emulsifier component. The water phase further comprises electrolytes such as calcium chloride from about 0.1% to 5%. And the oil phase comprises from about 1% to 10% of an oil-soluble reducing initiator or from about 1% to 10% of an oil-soluble oxidizing initiator, and from about 0.01% to about 5% of an emulsifier component. The oil phase may comprise 5% to about 50% by weight of a monomer component by weight of a rubbery co-monomer; (c) **from about 10% to about 40% of a cross-linking agent** and (d) from about 0.01% to about 5% of an emulsifier component that is soluble in the oil phase.

(emphasis added).

Accordingly, Applicants completely disagree with the Examiner's selective and narrow reading of paragraph [0022] to support a contention that Ko discloses porous materials that are substantially free of cross-linking and able to substantially fully dissolve in water. One of skill in the art reading the reference in its entirety would not immediately envision a product that is substantially free of cross-linking or able to substantially fully dissolve in water.

Applicants also disagree with the Examiner's contention that paragraph [0030] of Ko would suggest that Ko contemplated both water-soluble and water-insoluble materials. While this issue has not been formally introduced in the record, this was briefly discussed in a follow-up telephone call between the undersigned and Examiner Negrelli on April 18. Rather than suggesting that both water soluble and water insoluble products are disclosed, paragraph [0030] is merely a definition of the terms "water soluble" and "water insoluble." This paragraph does not explicitly refer to porous materials of the disclosure. In particular, the term "water soluble" appears only six more times in the specification of Ko: paragraph [0018] referring to water soluble monomers, paragraph [0022] referring to water soluble crosslinkers and water soluble SAP precursor monomers, paragraph [0038] referring to a water soluble electrolyte, paragraph [0053] referring to water soluble salts, and paragraph [0054] referring to water soluble oxidizing initiators. At no point does the disclosure describe a water soluble product or water soluble porous material.

Additionally, Applicants respectfully submit that Ko does not teach "at least partially freezing the aqueous phase" or "freeze drying the intermediate porous material" as described in claim 1. The Examiner argues that Ko provides this disclosure at paragraph [0032]. However, the statement to which the Examiner refers is merely in the definition of the term "solvent," and this is the only paragraph of the entire reference that refers to freeze-drying. Ko merely states in paragraph [0032] that "(f)or freeze-drying embodiments, the solvent used in the mixture of fibers and structuring composition needs to be capable of first freezing and then be capable of undergoing sublimation, wherein the solvent passes directly from its frozen state to a vapor state. As such, the solvent should have a freezing point at which the solvent changes from a liquid to a solid." However, no freeze-drying embodiments are described in the description of Ko's invention and there is no suggestion or guidance in the disclosure that provides a method for producing a water-soluble porous, polymeric material that comprises freeze drying. An aqueous solution is not mentioned in this paragraph. Elsewhere in the application, including descriptions of the specific embodiments, other methods of removing solvents are disclosed. For example, in paragraph [0044] Ko discloses that while the supercritical fluids can be vented away:

...remaining components of the oil phase may be removed after polymerization, if desired, by any known method, including pressing the foam to extrude oil, capillary wicking of the oil into an oil-absorbent blotter, vacuum removal or removal driven by an air pressure differential, stripping with heated gas or steam, heating to volatilize the oil or to decrease oil viscosity for easier mechanical removal, washing with a solvent such as acetone or other volatile organic fluid or washing with an aqueous solution comprising a surfactant for removal of the oil

phase, extraction with supercritical fluids such as supercritical carbon dioxide, and the like, or any combination thereof. Similar operations can be applied to remove any of the unpolymerized material (e.g., remaining water, emulsifier, initiators, surfactants, electrolytes, and the like) of the I-HIPE foam after polymerization of the superabsorbent precursor monomer(s) has occurred in the water phase. For example, water can be removed by air drying, by pressing and blotting, by air pressure differential across the I-HIPE foam, by heating, and the like, or any combination thereof. Water-soluble materials or unbound solids particles or loose fibers can be removed by any combination of washing with water, steam stripping, impinging with air jets, mechanical vibration, vacuum treatment, and the like.

Notably, freeze-drying is not mentioned among these various methods for removing residual components from the insoluble absorbent foams.

Finally, Applicants respectfully submit that the Examiner, in applying the disclosure of Ko to the pending claims, has interpreted the pending claims by improperly importing limitations or an intended use from the specification. Specifically, the Examiner alleged in paragraph 16 of the Office Action that "Ko et al. further teach that the polymeric foam is used to produce absorbent articles (paragraph [0063]), including bandages or wound dressings (wound healing matrices) (paragraph [0010]), which are disclosed uses for the porous materials of the instant invention. See paragraph [0026] of the Pre-Grant Publication of the instant application (US 2007/0135528)." The pending claims are directed to methods for producing a water-soluble porous polymeric material and water-soluble porous material obtained by the methods. The Federal Circuit has stated that "(t)hough understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim." *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). It also flows logically that water-soluble porous, polymeric material would not be useful in applications that require absorbent materials (e.g., bandages or wound dressings) as they would dissolve upon exposure to an aqueous medium. Dependent claim 30 was previously amended to remove a number of applications of the porous materials, including those mentioned by the Examiner. Accordingly, Applicants respectfully submit that it is clear that the pending claims would produce porous materials that would not be useful in such applications.

For at least the reasons given above, Applicants respectfully submit that independent claim 1 is not anticipated by Ko. Claims 2-6, 9-10, 13-15 and 17-20 depend either directly or ultimately from claim 1 and are accordingly not anticipated by Ko for at least the same and similar reasons. The lack of further discussion of these dependent claims is merely for the sake

of brevity, and should not be interpreted as acquiescing to any of the rejections of those claims. Applicants request reconsideration and withdrawal of the rejection.

Independent claim 26

Independent claim 26, as amended, reads as follows:

26. A water-soluble porous material comprising a water-soluble polymeric matrix, said water-soluble polymeric material being one or more chosen from the group consisting of water-soluble polysaccharides and water-soluble vinyl polymers, which matrix comprises substantially no residual organic solvent, said porous material being able to substantially fully dissolve in water at 20 °C.

For the same and similar reasons as those discussed above, Applicants submit that Ko does not disclose a water-soluble porous material as described in claim 26. Accordingly, claim 26 is not anticipated by Ko. Applicants request reconsideration and withdrawal of the rejection.

**Rejection under 35 U.S.C. § 103**

Claims 12, 16 and 23-30 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ko in further view of "Emulsion Templating Using High Internal Phase Supercritical Fluid Emulsions" by Butler et al. in *Advanced Materials* ("Butler"). Applicants respectfully disagree and traverse the rejection.

For at least the reasons set forth above, Ko does not teach or suggest the subject matter of independent claims 1 and 26. As Butler is merely asserted to disclose ranges of various components, it does not remedy the deficiencies of Ko. Accordingly, for at least the same and similar reasons as those addressed above, Applicants submit that claims 12, 16 and 23-25, which depend directly or ultimately from claim 1, and claims 27-30, which depend directly or ultimately from claim 26, are not obvious over Ko in view of Butler. Reconsideration and withdrawal of the rejection are respectfully requested.

### **CONCLUSION**

In view of the foregoing, Applicants submit that the claims are in condition for allowance. Favorable consideration of the present application as amended is therefore respectfully requested. If a conference call would be useful in resolving issues arising from the filing of this communication, please contact the undersigned at the below-noted number.

Respectfully submitted,

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